VALVULAR HEART DISEASE (TCTAP A-116 TO TCTAP A-123)

TCTAP A-116

Comparison of Aortic Annulus Dimensions by Multidetecter Computed Tomography Between Japanese and European Patients Undergoing Transcatheter Aortic Valve Implantation. Results from the Japanese Multicenter Registry and European Single Center Cohort

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BACKGROUND The purpose of this study was to compare directly the aortic annulus measurement by multi detector computed tomography (MDCT) between a Japanese multi-center registry and a European single-center experience undergoing transcatheter aortic valve implantation (TAVI).

METHODS Between October 2013 and July 2014, 90 patients who are undergoing TAVI were prospectively included in the OCEAN-TAVI registry from 3 Japanese centers (Keio university hospital, Toyohashi heart center, and Teikyo university hospital). Between March 20 09 and December 201 2, 181 consecutive patients undergoing TAVI who had pre-procedural MDCT at Institut Cardiovasculaire Paris Sud were prospectively included in the European cohort. We compared MDCT aortic annulus measurement of these 2 cohorts.

RESULTS Patients were of similar age (85.0 [Interquartile Range (IQR) 82.5-87.5] vs 84.0
[IQR 80.5-87.5] years, p=0.83), and body surface area was smaller in the Japanese registry (1.40±0.15 vs 1.76±0.00319, p<0.01). All annulus dimensions including short annulus diameter (19.4±2.0 vs 22.6±2.3, p<0.01), large annulus diameter (24.7±1.9 vs 27.6±2.5, p<0.01), calculated average annulus diameter by area (CAAD, 22.4±1.6 vs 25.6±2.2, p<0.01), left coronary ostium height (13.6 [IQR 12.0-15.0] vs15.1 [IQR 13.5-17.2] , p<0.01) and right coronary ostium height (15.9 [IQR 14.5-17.5] vs 17.7 [IQR 16.0-19.7] , p<0.01) were smaller in a Japanese registry. With hypothetical prosthesis sizing based on CAAD (20mm Edwards Sapien XT for <20 mm; 23mm: 20 to 22mm; 26mm: 22 to 25 mm; 29mm: >25 mm), the use of 20mm, 23mm, 26mm, and 29mm Edwards valve compared with a Japanese registry and an European cohort were 2.2% vs 0%, 51.1% vs 12.7%, 44.4% vs 43.1%, and 2.2% vs 44.2% (p<0.01), respectively.

CONCLUSION Japanese patients had smaller annulus dimensions by MDCT compared with European patients. Prosthesis sizing by CAAD showed smaller size of prosthesis would be required among Asian patients undergoing TAVI.

TCTAP A-117

Improvement of New York Heart Association (NYHA) Status in High Risk Patients with Severe Mitral Incompetence Following Percutaneous MitraClip Procedure

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BACKGROUND MitraClip has been increasingly performed in Asian countries since 2011. Our study is to evaluate the effectiveness of improvement of heart failure symptoms and functional status in heart failure patients with percutaneous method of reduction of mitral incompetence (MI) with the MitraClip system.

METHODS Patients were selected for the MitraClip procedure based on the consensus of the Heart Team in our center. Between February 2012 and December 2013, 24 patients considered high risk as surgical candidates undergone percutaneous therapy for severe MI using the MitraClip. All the patients underwent clinical and echocardiographic evaluation at baseline, and at 6-month follow-up. Mortality data, including cause of death, were collected.

RESULTS The mean age was 67 years (53-86), 58.3% (n = 14) was male with a mean logistic EuroSCORE of 21%. At baseline, 90% of patients were in New York Heart Association (NYHA) functional class III or IV and 46% of patients had a left ventricular ejection fraction (LVEF) ≤50%. 45.8% (n=11) patients presented with functional mitral regurgitation (FMR) and 54.2% (n=13) patients presented with degenerative mitral regurgitation (DMR). Procedural success was achieved in 96% of patients. Severity of MR was reduced in all successfully treated patients, 18 (75%) were discharged with MR ≤2+. There was improvement in the severity of MI at 6 months, compared with baseline (p < 0.0001), Thirty-day mortality was 6%. At 6 months, approximately 90% of patients had New York Heart Association functional class II or class I (p <0.0001).

CONCLUSION Results of the study demonstrate that mitral incompetence reduction with MitraClip treatment is effective, low risk, and leads to significant improvement in NYHA functional class in approximately 90% of patients with heart failure.

TCTAP A-118

12 Months Results from a CE Mark Trial of a 2nd Generation, Self-Expanding, Transfemoral Aortic Bioprosthesis for the Treatment of Patients with Severe Aortic Stenosis

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BACKGROUND A novel and innovative transfemoral aortic valve implantation (TF-AVI) system was used to treat 89 patients with severe aortic stenosis in a CE mark trial. This single-arm registry was performed at 6 clinical sites in Brazil, Germany and Japan. The first patient was implanted in January 2012 and the last study implant procedure took place in early October 2013.

METHODS These 89 high-risk patients afflicted with severe aortic stenosis were treated in single-arm trials conducted at 6 centers in Brazil, Germany and Japan. Treated patients have a mean age of 83.7 ± 4.4 years, an STS Score of 7.5 ± 8.2%, and a logistic EuroSCORE of 26.6± 7.7%. Baseline mean aortic gradient was 43.6 ± 17.1 mmHg and mean AVA was 0.7 ± 0.2 cm^2. Nearly all patients presented in NYHA ClassIII/IV at screening (n=84) and 65.2% were female. All patients provided EC-approved written informed consent.

RESULTS Procedure success rate was 94.4% (n=84) with 3 valve-in-valve procedures and 2 failed implantations due to one instance of annular rupture and one case of bioprosthesis leaflet tear. Both failed procedures occurred during post-dilatation. The implant procedures were performed using small, medium and large valves covering an annular range of 21 mm to 27 mm. At 30 days there were 3 deaths, 2 strokes and no MI reported. Only 8 new pacemaker implantations were required for a rate of 9.0%. Freedom from VARC II combined safety at 30 days was 84.3% (n=75). Echocardiography at 30 days revealed only 4 patients (4.9%) with moderate (grade 2) paravalvular leak – there were no patients with a paravalvular leak above grade 2. The mean gradient was reduced to 8.0 ± 2.9 mmHg and the aortic valve area was 1.8± 0.3 cm^2. At 12 months, all-cause mortality was 22.5% (n=20) with 3 additional strokes and one myocardial infarction reported.

CONCLUSION Outcomes from treatment with this new 2ndGeneration TF-AVI system confirm its feasibility of use and safety out to one year. In September 2014 this device received CE mark approval, and further postmarket data may be expected in the near future.

TCTAP A-119

Incidence and Procedural Outcome of Bicuspid Aortic Valve in 684 Patients Undergoing Transcatheter Aortic Valve Implantation

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BACKGROUND Data on transcatheter aortic valve implantation (TAVI)in bicuspid aortic valve (BAV) is rare and inconsistent, particularly concerning incidence and outcome. In part this might be attributed to an inadequate recognition of this condition and/or a relatively low sensitivity of echocardiography. However, multislice computed tomography (MSCT) is thought to have a better diagnostic accuracy.

The aim of this retrospective analysis was to review MSCTs for detection and classification of BAVs and verify the impact on procedural outcome.

METHODS Six-hundred-eighty-four consecutive patients with severe aortic stenosis who underwent TAVI in our institution between 2012 and 2014 with available pre-procedural MSCT were included. For adjudication of the leaflet phenotype, diastolic (70%) and systolic (30%) reconstructions were used. Genuine BAV was diagnosed according to Sievers *et al.* (type 0: purely bileaflet; type 1: trifleaflet anlage, 1 raphe; type 2: trileaftlet anlage, 2 raphes). Functional BAV was defined as tricuspid configuration with symmetric geometry of all three cusps and commissures in diastole - assuming a trileaftlet anlage - and bicuspid configuration during systole unmasking a fusion of two adjacent cusps. Device success according to VARC II criteria was compared between BAV and non-BAV patients.

RESULTS Mean age was 82.2± 5.9 years, logistic Euro score was 24.3 ± 12.2%, and 54.2% were female. With echocardiography only 15 (2.1%) cases were classified as BAV, whereas MSCT revealed a congenital BAV in 40 (5.8 %) cases (type 0, 1, and 2 in 7.5%, 77.5%, and 20% respectively). A trileaflet anlage with functional bicuspid anatomy was present in 13 (1.9%) patients. The overall incidence of functional and genuine BAV was much higher than diagnosed with pre-procedural echocardiography ($p = 0.001$).

In patients with BAV, the combined endpoint of device success according to VARC 2 was non-significantly lower than in those with tri-leaflet aortic valves (90.8% vs. 83.0%; $p = 0.07$). However, the rate of device-related procedural complications including device malpositioning, embolization and/or valve-in-valve implantation, was significantly higher in the BAV-group (11.3% vs. 3.2%; $p = 0.01$).

CONCLUSION MSCT facilitates the identification and classification of genuine or functional BAV in TAVI patients. Given a higher rate of procedural failures, a more attentive appreciation of a bicuspid phenotype should be encouraged.

TCTAP A-120

Effect of Successful Percutaneous Transvenous Mitral Commissurotomy for Mitral Stenosis on Pulmonary Function

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BACKGROUND Rheumatic Mitral valve stenosis still is an important cause of mortality and morbidity in certain parts of the world. Mostly the morbidity is manifested through pulmonary function limitations causing shortness of breath and poor tolerance to physical demands. These in turn is caused by chronic pulmonary circulatory changes from accumulation of water, proteins and proteoglycans in pulmonary interstitium. The degree of pulmonary involvement is directly manifested by the changes of pulmonary function test (PFT) and repair of mitral valve pathology shows significant improvement in PFT parameters as well as in symptoms. Percutaneous Transvenous Mitral Commissurotomy (PTMC) is an option to repair pure mitral stenosis with relatively less risk and economic burden.

METHODS A prospective study involving 58 patients of mitral stenosis having New York Heart Association (NYHA) II-IV class symptoms was done. Patients with favorable valve morphology (Wilkin's score<10) were selected for PTMC. Echocardiographic evaluation and PFT were done before and 7 days after PTMC and compared using paired student's T test and correlation between variables were established with Pearson's correlation analysis.

RESULTS Two patients died from procedural complication. Others showed significant improvement in symptoms and hemodynamic measurements after successful PTMC.

Before PTMC, 19 patients (33.9%) were in NYHA class III, 36 patients (64.3%) were in class II. After PTMC, majorities (37 patients, 66.1%) were switched over to NYHA class I and remaining 18 patients (32.1%) were in class II. Pulmonary artery systolic pressure did not show any correlation with forced vital capacity.

Echocardiographic Parameter	Group		p value
	Before PTMC	After PTMC	
Mitral valve area (square cm)	0.764 ± 0.1257	1.404 ± 0.1194	<0.001
Transmitral peak pressure gradient (mmHg)	26.43 ± 5.62	11.36 ± 2.4000	<0.001
Left atrial diameter (mm)	47.23 ± 5.350	40.18 ± 5.557	<0.001
Pulmonary artery systolic pressure (mmHg)	57.73 ± 17.03	31.27± 8.30	<0.001
Pulmonary function test findings			
FEV1 (% of predicted value)	60.18 ± 13.054	78.32 ± 11.874	<0.001
FVC (% of predicted value)	53.80 ± 12.313	68.57 ± 11.662	<0.001
FEV1/FVC	112.64 ± 16.292	114.98 ± 12.714	0.33
PEF (L/min)	223.75 ± 62.3215	372.05 ± 62.200	<0.001

CONCLUSION Patients with severe mitral stenosis have impaired pulmonary function which is of restrictive type. Symptom often does not correlate with the severity of the disease. Successful PTMC improves pulmonary function, as well as, clinical status. PTMC should be done in suitable cases to reduce morbidity in mitral stenosis. Also, assessment of lung function in patients with mitral stenosis may aid in timely decision-making before adopting the interventional strategy of treatment.

TCTAP A-121

Immediate and In-Hospital Outcome of Percutaneous Transvenous Mitral Commissurotomy in Patients with Mitral Restenosis After Previous Surgical Commissurotomy

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BACKGROUND Rheumatic fever and rheumatic heart disease continue to be the major health problem in all developing countries including Bangladesh. Percutaneous Transvenous mitral Commissurotomy (PTMC) is an established non-surgical modality for the treatment of severe rheumatic mitral valve stenosis. The purpose of this study was to evaluate our immediate and in-hospital results of Percutaneous Transvenous Mitral Commissurotomy (PTMC) in patients with restenosis with previous mitral surgery (CMC).

METHODS The study group included 880 consecutive patients who underwent PTMC at the National Institute of cardiovascular Diseases (NICVD), Dhaka and Al -Helal Heart Institute, Mirpur, Euro-Bangla Heart Hospital, Lalmatia, Dhaka between May 2003 and December 2012. Safety, efficacy and in-hospital results of percutaneous transvenous mitral commissurotomy were analyzed in 800 patients underwent PTMC without previous CMC (group 1) and compared with 60 those of with previous CMC (group 2).

RESULTS Baseline demographic and clinical characteristics were similar in the 800 patients without previous CMC (group-1) and the 80 patients with previous CMC (group-2) during the procedure. In the whole study group mitral valve area (MVA) was 0.85 ± 0.09 cm2 prior to PTMC, and increased to 1.76 ± 0.07 cm2 after the procedure ($p = 0.0001$). The mean increase in MVA was 0.78 ± 0.31 cm2 in the group-1 and 0.79 ± 0.41 cm2 in the group-2 (NS). During the procedure or in-hospital after PTMC, embolic events were recorded in 3 patients in group-1 and 2 patients ingroup-2 (NS). The frequency of minor hematoma at puncture site in 15 patients in group-1 vs. 13 patients in group-2 and the development of pericardial tamponade and urgent pericardiocentesis in 3 patients ingroup-1 vs. 3 patients in group-2 were similar in both groups.

CONCLUSION PTMC in selected patients with mitral restenosis after previous surgical commissurotomy (CMC) can be performed safely and with similar immediate efficacy and in-hospital outcome in patients with Mitral stenosis.